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EXAMINER	
HUYNH, CARLIC K	
ART UNIT	**PAPER NUMBER**
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,793	BUNTINX, ERIK	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-67,69-75,77-87,90 and 91* is/are pending in the application.

4a) Of the above claim(s) *41-48,51-53,56-67,69-71,73-75,77-87,90 and 91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-50,54-55 and 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *21 August 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks filed on August 1, 2007 is acknowledged.

Status of the Claims

1. Claims 41-91 are pending in the application, with claims 41-48, 51-53, 56-67, 69-71, 73-87, and 90-91 having been withdrawn from consideration, in response to the restriction requirement filed on March 14, 2007. Claims 68, 76, and 88-89 have been cancelled in an "Amendment – After Non-Final Rejection" filed on August 1, 2007. Accordingly, claims 49-50, 54-55, and 72 are being examined on the merits herein.

Response to Arguments

2. Applicants have amended the specification in an "Amendment-After Non-Final Rejection" filed on August 1, 2007 with respect to "Objection to the Abstract" have been fully considered and are persuasive. Applicants have amended the abstract to remove "said". Accordingly, in light of the amendments, the objection to the abstract has been withdrawn.

3. Applicants have amended the specification in an "Amendment-After Non-Final Rejection" filed on August 1, 2007 with respect to "Objection to the disclosure" have been fully considered and are persuasive. Applicants have amended the specification to correct the misspelling of "pipamperone". Accordingly, in light of the amendments, the objection to the disclosure or specification has been withdrawn.

4. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on August 1, 2007, with respect to "Rejections under 35 U.S.C. § 112, first paragraph" to claims 49, 54, 68, 72, and 88-89 have been fully considered and are persuasive. The Applicants have amended the claims to be directed to pipamperone. Thus, the Rejections under 35 U.S.C. § 112, first paragraph to claims 49, 54, 68, 72, and 88-89 have been withdrawn in light of the arguments and amendments.

5. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on August 1, 2007, with respect to "Rejections under 35 U.S.C. § 112, second paragraph" to claims 49-50, 54-55, 68, 72, and 88-89 have been fully considered and are persuasive. The Applicants have amended the claims to remove "such as". Thus, the Rejections under 35 U.S.C. § 112, second paragraph to claims 49-50, 54-55, 68, 72, and 88-89 have been withdrawn in light of the arguments and amendments.

6. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on August 1, 2007, with respect to "Rejections under 35 U.S.C. § 112, second paragraph" to claims 49-50, 54-55, 68, 72, and 88-89 have been fully considered and are persuasive. The Applicants have amended the claims from "a composition" as "a combined preparation...for separate or sequential use..." to "a pharmaceutical combined preparation". Thus, the Rejections under 35 U.S.C. § 112, second paragraph to claims 49-50, 54-55, 68, 72, and 88-89 have been withdrawn in light of the arguments and amendments.

7. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on August 1, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 49, 54, 68, and 72 have been fully considered and are persuasive in part. The reference Silver et al. (Neurology, 1998, Vol.

50, Suppl. 6, pp. S18-S22) does teach treating Parkinson's disease with carbidopa-levodopa (abstract). Thus, the Rejections under 35 U.S.C. § 103 to claims 49, 54, 68, and 72 employing Steiner et al. (US 6,300,354) and Hubble (European Journal of Neurology Suppl. 2000. Vol. 7. Suppl. 1. pp. 15-20) have been withdrawn in light of the arguments.

8. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on August 1, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 50 and 55 have been fully considered and are persuasive. The reference Mantelle et al. (US 5,446,070) does teach a combination of compounds. Thus, the Rejections under 35 U.S.C. § 103 to claims 50 and 55 have been withdrawn in light of the arguments.

9. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on August 1, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 88 and 89 have been fully considered. It is noted that claims 68, 76, and 88-89 have been cancelled in an "Amendment – After Non-Final Rejection" filed on August 1, 2007. Thus, the Rejections under 35 U.S.C. § 103 to claims 88-89 have been withdrawn in light of the amendments.

10. Applicant's arguments with respect to claims 49-50, 54-55, 68, 72, and 88-89 have been considered but are moot in view of the new ground(s) of rejection. The following new ground(s) of rejection to claims 49-50, 54-55, and 72 used herewith.

Claims 49-50, 54-55, and 72 are directed to a pharmaceutical combined preparation and thus intended use is not given any patentable weight.

Information Disclosure Statement

The Information Disclosure Statement submitted on August 21, 2007 is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Müller (Expert Opinion on Pharmacotherapy, 2002, Vol. 3, No 4, pp. 381-388) in view of PERMAX® prescribing information (http://www.fda.gov/medwatch/safety/2003/permax_PI.pdf, revised October 2, 2003, pp. 1-2).

Müller teaches a method for treating Parkinson's disease comprising antiparkinsonian drug (page 385). Müller further teaches that each antiparkinsonian drug may cause psychosis and thus treatment for Parkinson's disease should also include antipsychotic drugs such as pipamperone (page 385).

Müller does not teach pergolide.

PERMAX® prescribing information teaches that pergolide is used to treat Parkinson's disease (page 1). Pergolide is available as 0.05, 0.25, and 1 mg tablet dose formulations (page 1).

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the composition of

Müller to contain pergolide because the compounds of PERMAX® prescribing information are a composition of pergolide and according to PERMAX® prescribing information, compositions comprising pergolide may be used to treat Parkinson's disease.

The motivation to combine the compounds of Müller to the compounds of PERMAX® prescribing information is that the compounds of PERMAX® prescribing information are compositions comprising pergolide and that such compositions can be used to treat Parkinson's disease.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Regarding a pharmaceutical combined preparation as recited in claims 49 and 50, Müller teaches an antiparkinsonian drug may be combined with pipamperone to treat Parkinson's disease (page 385) and PERMAX® prescribing information teaches that pergolide is used to treat Parkinson's disease (page 1). Since both pipamperone and pergolide can be used to treat Parkinson's disease, it would be obvious that the agents can be combined in a combined pharmaceutical formulation for simultaneous, separate, or sequential administration.

Regarding the dose range of pipamperone as recited in instant claims 49 and 50, Müller teaches an antiparkinsonian drug may be combined with pipamperone to treat Parkinson's disease (page 385). Müller does not disclose a specific amount of pipamperone, only that

pipamperone can be used to treat Parkinson's disease. Thus it would be obvious that the method to treat Parkinson's disease in Müller may contain 5 to 15 mg of pipamperone.

Regarding the dose range of pergolide as recited in instant claim 50, PERMAX® prescribing information teaches that pergolide is available as 0.05, 0.25, and 1 mg tablet dose formulations, which meets the limitations of the instant claims (page 1). It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the quantity of pergolide provided in a composition, according to the guidance set forth in PERMAX® prescribing information, to provide a composition having the desired doses of pergolide in the pharmaceutical composition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

12. Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Müller (Expert Opinion on Pharmacotherapy, 2002, Vol. 3, No 4, pp. 381-388) in view of Silver et al. (Neurology, 1998, Vol. 50, Suppl. 6, pp. S18-S22).

Müller teaches a method for treating Parkinson's disease comprising antiparkinsonian drug (page 385). Müller further teaches that each antiparkinsonian drug may cause psychosis and thus treatment for Parkinson's disease should also include antipsychotic drugs such as pipamperone (page 385).

Müller does not teach carbidopa-levodopa.

Silver et al. teach carbidopa-levodopa is used to treat Parkinson's disease (page 818). The maximum dosage of levodopa is 600 to 800 mg and the maximum dosage of carbidopa is 75 to 100 mg (page 819).

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the composition of Müller to contain carbidopa-levodopa because the compounds of Silver et al. are a composition of carbidopa-levodopa and according to Silver et al., compositions comprising carbidopa-levodopa may be used to treat Parkinson's disease.

The motivation to combine the compounds of Müller to the compounds of Silver et al. is that the compounds of Silver et al. are compositions comprising carbidopa-levodopa and that such compositions can be used to treat Parkinson's disease.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Regarding a pharmaceutical combined preparation as recited in claims 54 and 55, Müller teaches an antiparkinsonian drug may be combined with pipamperone to treat Parkinson's disease (page 385) and Silver et al. teach carbidopa-levodopa is used to treat Parkinson's disease (page 818). Since both pipamperone and carbidopa-levodopa can be used to treat Parkinson's disease, it would be obvious that the agents can be combined in a combined pharmaceutical formulation for simultaneous, separate, or sequential administration.

Regarding the dose range of pipamperone as recited in instant claims 54 and 55, Müller teaches an antiparkinsonian drug may be combined with pipamperone to treat Parkinson's disease (page 385). Müller does not disclose a specific amount of pipamperone, only that pipamperone can be used to treat Parkinson's disease. Thus it would be obvious that the method to treat Parkinson's disease in Müller may contain 5 to 15 mg of pipamperone.

13. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Müller (Expert Opinion on Pharmacotherapy, 2002, Vol. 3, No 4, pp. 381-388) in view of Nystrom et al. (US 5,6345,213).

Müller teaches a method for treating Parkinson's disease comprising antiparkinsonian drug (page 385). Müller further teaches that each antiparkinsonian drug may cause psychosis and thus treatment for Parkinson's disease should also include antipsychotic drugs such as pipamperone (page 385).

Müller does not teach levodopa associated with benserazide.

Nystrom et al. teach L-dopa and benserazide as the active agents for the treatment of Parkinson's disease (column 8, lines 6-9).

It is noted that L-dopa is known in the art as levodopa.

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the composition of Müller to contain levodopa associated with benserazide because the compounds of Nystrom et al. are a composition of levodopa associated with benserazide and according to Nystrom et al., compositions comprising levodopa associated with benserazide may be used to treat Parkinson's disease.

The motivation to combine the compounds of Müller to the compounds of Nystrom et al. is that the compounds of Nystrom et al. are compositions comprising levodopa associated with benserazide and that such compositions can be used to treat Parkinson's disease.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Regarding a pharmaceutical combined preparation as recited in claim 72, Müller teaches an antiparkinsonian drug may be combined with pipamperone to treat Parkinson's disease (page 385) and Silver et al. teach carbidopa-levodopa is used to treat Parkinson's disease (page 818). Since both pipamperone and carbidopa-levodopa can be used to treat Parkinson's disease, it would be obvious that the agents can be combined in a combined pharmaceutical formulation for simultaneous, separate, or sequential administration.

Regarding the dose range of pipamperone as recited in instant claim 72, Müller teaches an antiparkinsonian drug may be combined with pipamperone to treat Parkinson's disease (page 385). Müller does not disclose a specific amount of pipamperone, only that pipamperone can be used to treat Parkinson's disease. Thus it would be obvious that the method to treat Parkinson's disease in Müller may contain 5 to 15 mg of pipamperone.

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 50 and 55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4 of copending Application Buntinx (US 2005/0203130).

The claim of Buntinx (US 2005/0203130) is directed to a method of treating a disease or disorder comprising administering pipamperone and a second compound, which may be levodopa or a dopamine receptor agonist such as pergolide. It is noted that claims 1 and 4 of Buntinx (US 2005/0203130) are drawn to a method comprising a composition of pipamperone and a second compound, the same pipamperone and pergolide or levodopa composition as recited in instant claims 50 and 55. Since claim 4 of Buntinx (US 2005/0203130) recites that the second compound can be levodopa or a dopamine receptor agonist such as pergolide, the claims of the instant application are rendered obvious over the claims of copending Application Buntinx (US 2005/0203130).

This is a provisional double patenting rejection since the conflicting claims have not been patented.

Conclusion

15. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh